Mr. Bruce Allen. Mr. Allen has 27 years of experience related to human and environmental health and safety. He has expertise as a biomathematician involved in risk assessment, modeling, statistical analysis, and clinical trials, having worked for a variety of government and private clients. Mr. Allen's primary interest is in the quantitative aspects of risk analysis, reflecting his experience with dose-response analysis; with the statistical appraisal of data, models, and modeling results; and with developing rigorous approaches to decision making in risk assessment contexts. His expertise in dose-response analysis extends to the modeling, including biologically motivated modeling, of cancer, noncancer, and genotoxic endpoints as well as genomics data. Mr. Allen's statistical expertise includes computer-intensive approaches – such as Monte Carlo simulation, bootstrap analysis, and Markov chain Monte Carlo approaches for Bayesian analyses – as well as other techniques for uncertainty analyses, data quality objectives, quality control/assurance, statistical analyses for site risk assessments, and analysis of clinical trials data. In particular, Mr. Allen has conducted research to study dose-response modeling approaches for developmental toxicants and analyzed cancer dose-response relationships and the issues associated with cancer risk assessment. In addition, Mr. Allen has participated in the development of methods that allow the estimation of risks from epidemiological data.

Mr. Allen received his B.S. in Mathematics and Philosophy from the University of Washington and his M.S. in Biomathematics with a Statistics minor from North Carolina State University. Mr. Allen has numerous publications in the areas of dose response modeling and was a contributor to U.S. EPA's assessment of 1,3-butadiene. Mr. Allen has provided expert testimony and has served as manager for numerous projects including multi-disciplinary, multi-year efforts.

Dr. Harvey Clewell. Dr. Clewell is Director of the Center for Human Health Assessment and a senior scientist in the Division of Computational Biology at The Hamner Institutes for Health Sciences. His duties at The Hamner include managing a research program on the use of biomonitoring results in exposure and risk assessment. Prior to joining CIIT, Dr. Clewell was a principal scientist for ENVIRON. He has over 25-years of experience in environmental quality research, toxicology research, chemical risk assessment, and hazardous materials management and is a leading expert on the use of tissue dosimetry and mode-of-action information in chemical safety and risk assessment. He is internationally known for his work in the applications of physiologically based pharmacokinetic (PBPK) modeling in cancer and non-cancer risk assessments, and was key to the first uses of PBPK modeling by EPA, ATSDR, OSHA, and FDA. In 2007 he received the Arnold J. Lehman Award from the Society of Toxicology for his contributions to risk assessment of chemicals, including pharmaceuticals.

Dr. Clewell received his B.A. in Chemistry from Bradley University, his M.A. in Physical Chemistry from Washington University, and his Ph.D. in Toxicology from the University of Utrecht. He is a Diplomate of the American Board of Toxicology. Dr. Clewell has authored numerous scientific publications, has provided testimony in both

civil tort cases and congressional hearings, and frequently provides invited lectures and computer workshops in the areas of pharmacokinetics and risk assessment. He has also served on a number of external peer review panels for EPA, ATSDR, and Health Canada, including the peer review panel that evaluated Health Canada's Assessment of 1,3-butadiene.

Dr. George Daston. Dr. George Daston is a Research Fellow for the Procter & Gamble Company (P&G) where he has worked since 1985. He has worked the past 21 years in the field of developmental toxicology and risk assessment, particularly in the area of children's risk assessment. Dr. Daston is also an adjunct professor in the Department of Pediatrics and Developmental Biology Program at the University of Cincinnati and Children's Hospital Research Foundation, and lectures in courses on teratology, developmental biology, toxicology, and risk assessment. Dr. Daston received his Ph.D. in Developmental Biology and Teratology and a B.S. in Biology from the University of Miami. Prior to joining the Procter & Gamble Company, Dr. Daston worked for the U.S. EPA's Health Effects Research Laboratory as a National Research Council Research Associate and as an assistant professor for the Department of Biological Sciences at the University of Wisconsin. His research interests include teratogenic mechanisms, *in vitro* methodologies, and risk assessment. His most recent research includes toxicant-nutrient (especially zinc) and maternal-embryonal interactions in developmental toxicity, the role of pattern formation genes in abnormal development, genomic approaches to endocrine disrupter screening, and improvements in risk assessment methodology for noncancer endpoints.

Dr. Daston's activities in professional societies include serving as Chair of the Reproductive and Developmental Effects Subcommittee of the American Industrial Health Council, Chair of the Developmental and Reproductive Toxicology Technical Committee of ILSI-Health Effects Sciences Institute; President of the Society of Toxicology's Reproductive and Developmental Toxicology Specialty Section, President of the Teratology Society, member of the National Academy of Sciences Board on Environmental Studies and Toxicology, and member of EPA's Endocrine Disrupter Screening and Testing Advisory Committee (EDSTAC). Dr. Daston has recently served on the organizing committees for an ILSI/EPA/AIHC workshops on benchmark dose methodology and human variability in toxic response; an EPA workshop on endocrine mediated toxicity; and as co-chair of an AIHC/EPA workshop on Leydig cell tumors, an ILSI/EPA workshop on interpreting reproductive toxicity endpoints, and a NIEHS workshop on the state of validation of the FETAX assay for teratogen screening.

Dr. Daston is an Associate Editor of *Toxicological Sciences*, Editor-in-Chief of *Birth Defects Research Part B: Developmental and Reproductive Toxicology*, on the Editorial Board of *Human and Ecological Risk Assessment* and *Reproductive Toxicology*, and an ad hoc reviewer for *Teratology, Journal of Nutrition* and other journals. He has published over 90 peer-reviewed articles, reviews and book chapters, and has edited three books.

Dr. Dave Gaylor. Dr. Gaylor, whose expertise is in the fields of biometry, statistics, and health risk assessment retired from the National Center for Toxicological Research (NCTR), FDA, where he served as the principal advisor to the NCTR Director/FDA Associate Commissioner for Science on matters related to the planning, development, implementation and administration of health risk assessment policies reaching across a wide range of FDA's activities. In a prior position with the NCTR, he was Director of the Biometry and Risk Assessment Division where he was responsible for the administration and scientific direction of the Biometry and Risk Assessment program. In that position, he developed experimental protocols and provided statistical analyses of experiments in carcinogenesis, teratogenesis, mutagenesis, and neurotoxicity, and developed techniques to advance the science of quantitative health risk assessment. Dr. Gaylor also serves as an Adjunct Professor of Statistics at the University of Arkansas for Medical Sciences, Little Rock. He is a Fellow of the American Statistical Association, the Society for Risk Analysis, and Academy of Toxicological Sciences and he is a member of the Biometric Society, Society for Regulatory Toxicology and Pharmacology, and the Teratology Society. Dr. Gaylor has served on more than 80 national and international work groups and committees on many aspects of biometry, toxicology, and risk assessment. He is currently a member of the editorial board of: Risk Analysis, Human and Ecological Risk Assessment, Toxicology and Industrial Health, and Regulatory Toxicology and Pharmacology. Dr. Gaylor has also authored or coauthored more than 160 journal articles, 28 book chapters, and made over 120 presentations at scientific meetings on bio-statistics and a wide range of health risk assessment issues.

Dr. Lynne Haber. Dr. Haber is a Senior Scientist and Director of the Research Program at *TERA*. She has 17 years of experience in development of assessment documents, evaluating toxicity, toxicokinetics, and epidemiology studies, and in risk assessment methods development. She has conducted a variety of toxicological assessments, including evaluating and synthesizing data from acute, subchronic, and chronic animal and human toxicity studies, as well as toxicokinetics data, for more than 30 major documents for the U.S. EPA's Office of Water, other EPA offices, and other government agencies. She has developed numerous RfDs, RfCs, and cancer assessments, including a number of assessments conducted under updated versions (1996-2005) of U.S. EPA's carcinogen assessment guidelines, as well as a number of health advisories for shorter exposure durations. Dr. Haber's research interests include the improved use of mechanistic data in risk assessment, including incorporation of mode of action data in cancer risk assessment, and use of data to replace default uncertainty factors. She has served as a panel chairperson or panel member for scientific peer reviews organized by *TERA*, EPA, and other U.S. and foreign government agencies. She has also served on two panels for the NAS/NRC. Her quantitative experience includes serving on a peer review committee for EPA's Benchmark dose guidelines, participating in a workshop on benchmark dose (BMD) and categorical regression, and several publications on issues related to BMD and categorical regression modeling. She has also used both BMD modeling and categorical regression modeling in the development of acute and chronic risk values. Dr. Haber's experience covers all aspects of human health risk assessment

including inhalation, oral and dermal toxicology, acute and chronic hazard identification and dose-response for cancer and non-cancer risk assessment and regulatory toxicology.

Dr Haber received her B.S. in Chemistry from University of California, Los Angeles and her Ph.D. in Biology from Massachusetts Institute of Technology. She is a Diplomate of the American Board of Toxicology. Dr. Haber has numerous peer reviewed publication on risk assessment methods and chemical-specific risk assessment. Her published work includes lead authorship of the chapter on noncancer risk assessment (including dose-response modeling methods) for Patty's Toxicology, and an invited review on the use of mechanistic data in risk assessment. She was also the coauthor for an analysis of the effect of genetic polymorphisms on human variability in dose, using PBPK and Monte Carlo modeling. She has published on methods for deriving occupational exposure limits, and on incorporating toxicokinetic data into risk assessment.

Dr. Rogene Henderson. Dr. Henderson is a Senior Scientist Emeritus at the Lovelace Respiratory Research Institute in Albuquerque, NM. Dr. Rogene Henderson has research interests in three major areas. She has had a long-term interest in the biochemistry of the lung, particularly the surfactant lining layer. She has developed *in vivo* screening tests for pulmonary toxicants based on analysis of bronchoalveolar washings for biomarkers of lung injury and repair. A second area of her research has been on the mechanisms by which pulmonary inflammation leads to repair or to chronic disease (fibrosis, emphysema). A third area of interest is the pharmacokinetics of inhaled xenobiotics (particularly vapors) and chemical-specific biomarkers of chemical exposure. She has served on numerous NAS committees and EPA external peer review panels, including a peer review panel that provided guidance on setting acute exposure reference standards. In addition, in June 2007, Dr. Henderson served on the IARC Work group evaluating the carcinogenicity of 1,3-butadiene.

Dr. Henderson received her B.S./B.A. in Chemistry from Texas Christian University and her Ph.D. in Chemistry from University of Texas. She has over 230 peer-reviewed publications and has served on the editorial board of several journals, including *Toxicology*, *Journal of Biochemical Toxicology*, *Inhalation Toxicology, Toxicology and Applied Pharmacology*, and *Journal of Exposure Analysis and Environmental Epidemiology*. Dr. Henderson was selected for this panel based on her expertise in inhalation toxicology and pharmacokinetics of inhaled toxicants as well as her extensive experience serving on advisory and peer review panels.

Dr. Kyle Steenland. Dr. Steenland is a Professor of Epidemiology in the Department of Environmental and Occupational Health at Emory University's Rollins School of Public Health. Prior to joining Emory University, Dr. Steenland served as an Epidemiologist for the National Institute for Occupational Safety and Health and for the International Agency for Research on Cancer. Dr. Steenland has been an investigator in epidemiological studies to evaluate the relationship between risk of disease and occupational exposure to numerous chemicals, including dioxin, polychlorinated

biphenyls, silica, lead, ethylene oxide, and pesticides. His current research interests include Alzheimer's and Parkinson's disease, as well as a comprehensive cohort study on the health effects of Perfluoroctanoate. Dr. Steenland has served on Federal Advisory Committees, including the National Toxicology Program's work group evaluating lead carcinogenicity, and an EPA committee to develop a criteria document on lead carcinogenicity.

Dr. Steenland received his BA in History from Stanford University, a PhD in history from the University of New York at Buffalo, a PhD in Epidemiology from the University of Pennsylvania and a Masters in Mathematics from the University of Cincinnati. He is a Fellow of the American College of Epidemiology, a member of the International Congress on Occupational Health, and Editor of the journals *Epidemiology* and *American. Journal of Industrial Medicine*. Dr. Steenland has numerous peer reviewed publications on epidemiological methods and chemical-specific epidemiology studies, and he has edited two books on occupational and environmental epidemiology.